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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/486,971	05/19/00	LEHTOLA V	933-154PCT

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EXAMINER	
BENNETT,R	
ART UNIT	**PAPER NUMBER**
1615	7

DATE MAILED: 10/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/486,971	LEHTOLA ET AL.	
	Examiner	Art Unit	
	Rachel M. Bennett	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *19 July 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☒ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☒ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

1. The examiner acknowledges receipt of Preliminary Amendment and Information Disclosure Statement received on 5/19/00 and Letter submitting additional documents for entering national phase filed on 7/19/00.

2. The specification is objected to because this application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Specification

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10 is rejected under 35 U.S.C. 112, 2, because the claimed recitation of use, provides for the use of silicified microcrystalline cellulose for the manufacture of a pharmaceutical preparation, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 10 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e.,

results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-7, 9-10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Posti et al (US 5525354).

Posti discloses a pharmaceutical preparation for oral use containing a pharmacologically acceptable salt of a dichloromethylene bisphosphonic acid, a clodronate, especially disodium clodronate (see abstract, column 1 lines 6-10). The preparation may also contain additives, such as carriers, diluents, fillers, lubricants, and disintegrating agents, which are all known in the art (see column 2 lines 18-22). More specifically, microcrystalline cellulose as a filler and colloidal silicon dioxide may be used as a lubricant (see column 2 lines 41-51). The preparation is carried out using known tabletting, granulating or pelletization techniques (see column 2 lines 52-54). Example 1 illustrates a tablet comprising disodium clodronate, microcrystalline cellulose and silicon dioxide. The desired amount of clodronate can vary within wide limits from 10 to 95% by weight (see column 2 lines 22-25). The preparation also comprises of silicified microcrystalline cellulose comprises about 8 to 20% by weight, and lubricants and/or

disintegrants comprise about 0.5 to 10% by weight (see example 1). Therefore these claims are anticipated.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Posti et al. (US 5525354).

Posti, as disclosed above, teaches a pharmaceutical preparation containing the active ingredient disodium chodronate with an enteric coating. Posti does not specifically teach the process of dry granulation.

It is the position of the examiner that it would be obvious to one of ordinary skill in this art, at the time of invention, by routine experimentation, to omit the water and/or ethanol from the preparation in order to achieve the applicant's goal of dry granulation because the reference teaches the preparation is carried out using known granulating techniques and dry granulation is well known in the art (see column 2 lines 40-54). The reference also desires a tablet with an enteric coating. Applicant's claims do not exclude the addition of an enteric coating. The expected result would be pharmaceutical preparation containing the active ingredient disodium clodronate with silicon dioxide and microcrystalline cellulose and lubricants and/or disintegrating agents in order to provide an oral solid dosage form compressed into a tablet.

Art of Interest

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sherwood et al. WO 96/21429 discloses microcystalline cellulose particles and silicon dioxide in an agglomerate used as an excipient.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 309-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

RMB
October 17, 2000

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600